

# **EXHIBIT 170**

**HIGHLY CONFIDENTIAL — SUBJECT TO PROTECTIVE ORDER**

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	)	
<i>This document relates to:</i>	)	<b>MDL 2804</b>
City of Cleveland, et al. v. Purdue Pharma L.P., et al., Case No. 18-OP-45132;	)	<b>Case No. 17-md-2804</b>
	)	<b>Hon. Dan Aaron Polster</b>
County of Cuyahoga, et al. v. Purdue Pharma L.P., et al., Case No. 17-OP-45004;	)	<b>Mag. Judge David A. Ruiz</b>
	)	
County of Summit, et al. v. Purdue Pharma, L.P. et al., Case No. 18-OP-45090	)	

**EXPERT REPORT OF WILLIAM S. CHOI, PH.D.**

**May 10, 2019**

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3. In reality, CVS had in place SOM programs, which flagged potentially suspicious orders and had a process to evaluate those flagged orders. From 2009 to 2014, CVS adopted and evolved an approach that utilized a modified logit regression model to identify potentially suspicious orders (“CCS-SOM”).<sup>7</sup> CVS subsequently replaced the CCS-SOM with an alternative algorithm (“AGI-SOM”) in early 2014.<sup>8</sup> Both algorithms were designed to flag for further review orders that may be of unusual size, unusual frequency, and exhibiting an unusual pattern. It is my opinion that these algorithms, from a statistical standpoint, were reasonable approaches for identifying potentially suspicious orders (*i.e.*, outliers) and are consistent with my understanding of the DEA’s criteria for distributors.

4. Plaintiffs’ experts have not provided a substantive critique of these algorithms nor how such algorithms would have needed to be improved to meet DEA requirements. Instead, Plaintiffs’ experts have simply disregarded entirely the CVS SOMs and imposed their own extreme methodologies that are not grounded in reality nor have a statistical basis.

## **II. Qualifications**

5. I am a Managing Director in the professional services firm AlixPartners, LLC (“AlixPartners”). I have extensive experience in economic, financial, and statistical

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<sup>7</sup> CVS-MDLT1-000123386 to CVS-MDLT1-000123392, CVS-MDLT1-000114642 to CVS-MDLT1-000114652, and CVS-MDLT1-000109623 to CVS-MDLT1-000109625.

<sup>8</sup> CVS-MDLT1-000018670 to CVS-MDLT1-000018674.

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in connection with changes to the algorithm from time to time thereafter while the CCS-SOM was in use by CVS from 2009 to 2014. CVS implemented a new SOM computer algorithm developed with Analysis Group, Inc. (“AGI-SOM”) in early 2014.<sup>33</sup>

**C. CVS’s SOM Systems are and were Based on Reasonable Statistical Methods**

**a) CCS-SOM Applies Established Statistical Tools Consistent with DEA Criteria**

21. I have reviewed the supporting documents related to the CCS-SOM.<sup>34</sup> The CCS-SOM is a series of iterations on an approach for identifying potentially unusual orders. The CCS-SOM takes into account order sizes, ordering frequency, and ordering pattern, which is consistent with my understanding of the concepts set forth in the DEA regulation.

22. The CCS-SOM is based on a modified logit regression model (“logit model”), which is a statistical tool used to analyze binary data. The logit model is commonly used in

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<sup>33</sup> CVS-MDLT1-000018670 to CVS-MDLT1-000018674

<sup>34</sup> CVS-MDLT1-000123386 to CVS-MDLT1-000123392, CVS-MDLT1-000114642 to CVS-MDLT1-000114652, CVS-MDLT1-000075541, CVS-MDLT1-000088409, CVS-MDLT1-000088410 to CVS-MDLT1-000088411, CVS-MDLT1-000088412 to CVS-MDLT1-000088433, CVS-MDLT1-000088434 to CVS-MDLT1-000088515, CVS-MDLT1-000088577, CVS-MDLT1-000088578, CVS-MDLT1-000088726 to CVS-MDLT1-000088729, CVS-MDLT1-000111189 to CVS-MDLT1-000111190, CVS-MDLT1-000111191 to CVS-MDLT1-000111200, CVS-MDLT1-000111210 to CVS-MDLT1-000111218, CVS-MDLT1-000111219 to CVS-MDLT1-000111227, CVS-MDLT1-000111228 to CVS-MDLT1-000111236, CVS-MDLT1-000111257 to CVS-MDLT1-000111259, CVS-MDLT1-000111260 to CVS-MDLT1-000111262, CVS-MDLT1-000111309 to CVS-MDLT1-000111311, CVS-MDLT1-000111435 to CVS-MDLT1-000111437, CVS-MDLT1-000109623 to CVS-MDLT1-000109625, CVS-MDLT1-000088734 to CVS-MDLT1-000088737, CVS-MDLT1-000088523 to CVS-MDLT1-000088524, CVS-MDLT1-000110439 to CVS-MDLT1-000110441.

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economics to model the likelihood of a particular outcome. For example, a logit model can be used to estimate the likelihood that a mortgage application is denied and whether that outcome is tied to race.<sup>35</sup> Other applications include how tuition support affects students' decisions to attend college, as well as factors that determine whether a teenager starts smoking, whether a country receives foreign aid, or whether a job applicant is successful.<sup>36</sup> I have regularly used the logit model throughout my career as an applied economist, including loan scoring for purposes of identifying loans that were in compliance with guidelines on behalf of the Department of Justice in its investigations of mortgage fraud.

23. In a logit model, the binary variable of interest is the dependent variable (*i.e.*, the “Y” variable that we want to explain), and the model quantifies the relationship between the dependent binary variable (*e.g.*, whether an order is deemed to be unusual) on a set of explanatory variables (the “X” variables that are used to explain the outcome). The standard logit model estimates the likelihood that an order will be found to be unusual upon further evaluation. The estimated coefficients from the logit model can be used to compute the relative likelihood that the order is unusual.

24. The binary question addressed by the CCS-SOM is whether an order is cleared for shipment or is listed for further evaluation. The CCS-SOM examines shipment data at the pharmacy store level, and it is my understanding that the logit model was

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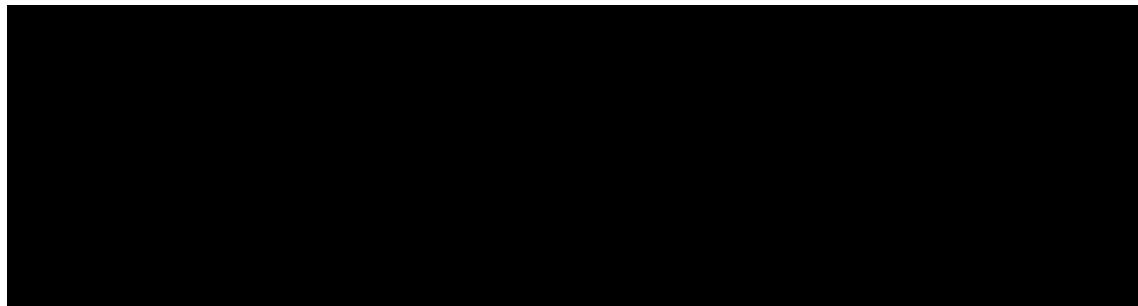
<sup>35</sup> Stock, J.H. and M.W. Watson, *Introduction to Econometrics*, 3<sup>rd</sup> ed., Pearson, 2015, pp. 396-397.

<sup>36</sup> Stock and Watson, p. 386.

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developed using CVS's data.<sup>37</sup> The CCS-SOM model initially included explanatory variables based on the prior six months' orders, which later was expanded to the prior twelve months' orders.<sup>38</sup>

25. An initial iteration of the CCS-SOM system was delivered to CVS in December 2008. For each order, a historical data table was created, which included the total amount of the NDC item that a given store had ordered during the prior six months. The CCS-SOM calculated a series of indicator variables (also known as "dummy" variables) and statistics based on historical data. The algorithm calculated six order attributes that incorporated these historical indicator variables and statistics, as well as current order specifications, and the cumulative amount ordered in the current month including the order in question. Each of these order attributes reflects one of the dimensions referenced in the DEA regulation:



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<sup>37</sup> Deposition of Henry John Mortelliti, dated January 23, 2019, Exhibit 615 (CVS-MDLT1-000034183). Exhibit 611 (CVS-MDLT1-000109625). Exhibit 610 (CVS-MDLT1-000114643).

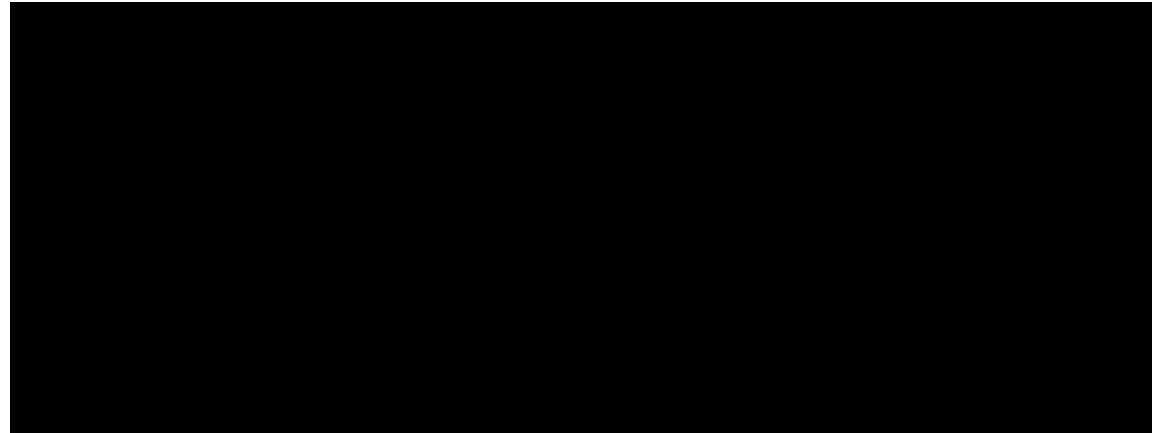
Cegedim Dendrite Descriptive Overview Document: Cegedim Dendrite Suspicious Order Monitoring (SOM) Model, p. 7 (CVS-MDLT1-000123392).

<sup>38</sup> CVS-MDLT1-000114644.

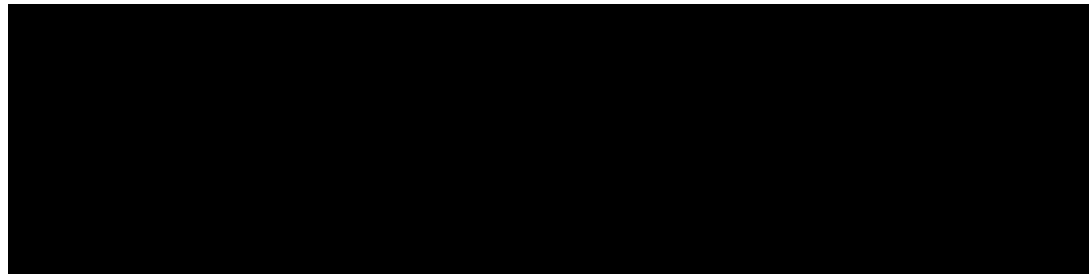
<sup>39</sup> CVS-MDLT1-000123389. The attribute is bounded by 5 and -5.

<sup>40</sup> CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute is bounded by 5 and -5.

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The CCS-SOM then uses these six attributes to calculate an index for each order using predetermined regression coefficients supplied by CCS, as shown below.



The resulting statistic,  $s$ , in the equation above, is then compared to a predetermined threshold – 0.15 in the first iteration of the CCS-SOM – to determine whether the order should be flagged for further scrutiny.

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<sup>41</sup> CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute tests if the last order was within five days.

<sup>42</sup> CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute tests if the cumulative order total is greater than the previous month and the slope of the historical ordering is positive.

<sup>43</sup> CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute is classified as an “override attribute” that seeks to reduce the likelihood of false positives.

<sup>44</sup> CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute is classified as an “override attribute” that seeks to reduce the likelihood of false positives.

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26. After several months of usage, CVS staff informed CCS that the model was “pending a large number of orders that were not suspicious on their face and cleared by CVS staff.”<sup>45</sup> As CCS noted at the time, this may happen during the initial implementation of a model reliant on static data. CCS re-calculated the logit regression coefficients and delivered updated values to CVS on August 27, 2009.<sup>46</sup> These new coefficients can be seen in the Item Review Report from September 4, 2009.<sup>47</sup> Notwithstanding the recalculation of coefficients, CVS personnel determined the system was still pending a large number of orders that were not deemed to be suspicious. On February 15, 2010, Robert Williamson of CCS, responding to CVS in regards to excess false-positives, stated

... a superior option would be to raise the magnitude of the score required to pend an order. The score used for pending is currently .15. We recommend that you have your IT staff adjust this score upwards in small increments until you can determine that the pended orders may be suspicious.<sup>48</sup>

Between March 2010 and July 2010, John Mortelliti, along with CVS Field Loss Prevention, reviewed test IRR reports with increasing index thresholds in order to determine an appropriate level and reduce the incidence of too many false positives. On July 2, 2010, Mr. Mortelliti recommended changing the index threshold from 0.15 to 0.65, and he “verified recommendations from field [Loss Prevention personnel].”<sup>49</sup> According to

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<sup>45</sup> CVS-MDLT1-000114642.

<sup>46</sup> CVS-MDLT1-000109623 to CVS-MDLT1-000109625.

<sup>47</sup> CVS-MDLT1-000024949.

<sup>48</sup> CVS-MDLT1-000110441.

<sup>49</sup> CVS-MDLT1-000088411.

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an internal memo on August 13, 2010, “the IRR score was eventually adjusted to .65.”<sup>50</sup> The earliest IRR that I have seen showing the index threshold change was September 28, 2010.<sup>51</sup>

27. On February 9, 2011, CCS delivered a second iteration of the CCS-SOM system with a revised algorithm and with new attributes.<sup>52</sup> According to CCS, the adjustment – and future adjustments – “afford[ed] an opportunity for the attributes to be reconfirmed to ensure that the most appropriate order information is collected and analyzed in an appropriate manner.”<sup>53</sup> Several changes were made to the model:

- inclusion of both a six-month and a twelve-month historical table,
- conversion to milligrams of active ingredients as the quantity variable so that order comparisons are made on the basis of active ingredient rather than distinguished by brand, formula, or package size, and
- specific new attributes to account for an over-inclusion of false-positives.

Consistent with the first iteration, the CSS-SOM calculates a series of indicator variables and statistics based on six-month and now twelve-month historical data. The model relies on nine order attributes, five binary indicators, and four continuous variables, which are calculated incorporating the historical indicator variables and statistics, current order specifications, and the cumulative amount ordered in the current month (including the order in question).

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<sup>50</sup> CVS-MDLT1-000088578.

<sup>51</sup> CVS-MDLT1-000100722 to CVS-MDLT1-000100729

<sup>52</sup> CVS-MDLT1-000114644.

<sup>53</sup> CVS-MDLT1-000114642.

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28. The second iteration of the CCS-SOM system has several improvements over the initial CCS-SOM system. The CCS-SOM system monitors based on milligrams of active ingredient; this is in contrast to the initial CCS-SOM that monitored by product (*i.e.*, Vicodin and not hydrocodone) and also by number of doses (*i.e.*, number of pills). The second iteration measures the volume or quantity by the active ingredient and aggregates that across all products with the same active ingredient. The initial CCS-SOM system applied the same criteria to all orders—that is, the same variables were evaluated using the same coefficients for all orders. The second iteration of the CCS-SOM system evaluated orders from pharmacies that had more frequent orders over the past twelve months differently from orders from pharmacies that had less frequent orders over the past twelve

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<sup>54</sup> CVS-MDLT1-000114650.

<sup>55</sup> CVS-MDLT1-000114650.

<sup>56</sup> CVS-MDLT1-000114650.

<sup>57</sup> CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute tests if the cumulative order total is greater than the previous month and the slope of the historical ordering is positive.

<sup>58</sup> CVS-MDLT1-000123389 to CVS-MDLT1-000123390. The attribute tests if the last order was within five days.

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months.<sup>59</sup> More frequent orders are evaluated using a number of criteria reflecting both six and twelve month historical data and ordering trends whereas less frequent orders are evaluated using twelve month historical data and without trends information.

**b) Criticisms by Messrs. Rafalski and Whitelaw of the CCS-SOM are Unfounded**

29. I have been asked to focus on certain portions of the Whitelaw and Rafalski Reports that address the CCS-SOM and AGI-SOM. Of the Plaintiffs' Expert Reports that I have referenced and reviewed, Messrs. Whitelaw and Rafalski are the only two who have criticized CVS's SOM systems.

30. Mr. Whitelaw bases his assessment on a "Compliance Maturity & Program Effectiveness Model"<sup>60</sup> and opines that the distributors' compliance programs, including CVS, were inadequate, and he characterized CVS's compliance programs as "remedial."<sup>61</sup> Mr. Whitelaw writes he understands that the CCS-SOM method sought "to apply statistical techniques to establish 'norms' and 'deviations' in order that the overall 'suspiciousness' of the order [could] be evaluated," therefore "[a]t its core, the system [used] a heavily modified

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<sup>59</sup> Deposition of Henry John Mortelliti, dated January 23, 2019, Exhibit 610, (CVS-MDLT1-000109625).

Cegedim Dendrite Descriptive Overview Document: Cegedim Dendrite Suspicious Order Monitoring (SOM) Model (CVS-MDLT1-000114650-51).

CVS-MDLT1-000123389-90, CVS-MDLT1-000123389-92.

<sup>60</sup> Whitelaw Report, p. 43. Though Dr. Whitelaw describes it as the "best approximation of a standardized scoring model" of compliance effectiveness, he provides no evidence that this approach is a generally accepted practice, nor does he explicitly cite to any literature to support his methodology.

<sup>61</sup> Whitelaw Report, p. 161.